

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON**

UNITED STATES OF AMERICA,

Plaintiff,

v.

**JAMES G. COLE, an individual, JAMES G.
COLE, INC., a corporation, JULIE D.
GRAVES, an individual,**

Defendants.

Case No. 3:13-cv-01606-SI

OPINION AND ORDER

S. Amanda Marshall, United States Attorney, Ronald K. Silver, Assistant United States Attorney, United States Attorney's Office, District of Oregon, 1000 S.W. Third Avenue, Suite 600, Portland, OR 97204; Stuart F. Delery, Assistant Attorney General, Maame Ewusi-Mensah Frimpong, Deputy Assistant Attorney General, Michael S. Blume, Director, Consumer Protection Branch, and Ann F. Entwistle, Trial Attorney, Consumer Protection Branch, United States Department of Justice, Liberty Square Building, Room 6231, 450 Fifth Street, NW, Washington, D.C. 20530. Of Attorneys for Plaintiff.

John J.E. Markham, II, Markham & Read, One Commercial Warf West, Suite 2000, Boston, MA 02110; Krista M. Shipsey, Law Office of Krista Shipsey, 820 S.W. Second Avenue, Suite 275, Portland, OR 97204. Of Attorneys for Defendants.

Michael H. Simon, District Judge.

Plaintiff, the United States of America (the "Government"), brings this action under 21 U.S.C. § 332(a) to enjoin Defendants James G. Cole, James G. Cole, Inc., and Julie D. Graves (collectively "Defendants"), from further distributing products that allegedly violate the Federal Food, Drug, and Cosmetic Act ("FDCA"). Specifically, the Government alleges that Defendants are acting in violation of: 21 U.S.C. § 331(d), by introducing or distributing into interstate commerce new drugs without review by the Federal Drug Administration ("FDA"); 21 U.S.C.

§ 331(a), by introducing misbranded drugs into interstate commerce; 21 U.S.C. § 331(k) and 21 U.S.C. § 352(f)(1), by offering for sale misbranded drugs lacking adequate directions for use after the drugs' shipment in interstate commerce; 21 U.S.C. § 331(a) and 21 U.S.C. § 342(g)(1), by distributing into interstate commerce adulterated articles of food (dietary supplements); and 21 U.S.C. § 331(k) and 21 U.S.C. § 342(g)(1), by causing articles of food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become adulterated.

Before the Court is the Government's Motion to Dismiss Defendants' Counterclaim and Strike Defendants' Affirmative Defenses (ECF 11) under Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), and 12(f). For the reasons set forth below, the Government's motion is granted in part and denied in part.

STANDARDS

A. Motion to Dismiss Under Rule 12(b)(1)

Federal courts are courts of limited jurisdiction. *Gunn v. Minton*, 133 S. Ct. 1059, 1064 (2013) (citation omitted). As such, a court is to presume "that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (citations omitted); *see also Robinson v. United States*, 586 F.3d 683, 685 (9th Cir. 2009); *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) for lack of "subject-matter jurisdiction, because it involves a court's power to hear a case, can never be forfeited or waived." *United States v. Cotton*, 535 U.S. 625, 630 (2002). An objection that a particular court lacks subject-matter jurisdiction may be raised by any party, or by the court on its own initiative, at any time. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 506 (2006); Fed. R. Civ. P. 12(b)(1). The Court must dismiss any case over which it lacks subject-matter jurisdiction. Fed. R. Civ. P. 12(h)(3).

A Rule 12(b)(1) motion to dismiss for lack of subject-matter jurisdiction may be either “facial” or “factual.” *See Safe Air for Everyone*, 373 F.3d at 1039. A facial attack on subject-matter jurisdiction is based on the assertion that the allegations contained in the complaint are insufficient to invoke federal jurisdiction. *Id.* “A jurisdictional challenge is factual where ‘the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction.’” *Pride v. Correa*, 719 F.3d 1130, 1133 n.6 (9th Cir. 2013) (quoting *Safe Air for Everyone*, 373 F.3d at 1039)). When a defendant factually challenges the plaintiff’s assertion of jurisdiction, a court does not presume the truthfulness of the plaintiff’s allegations and may consider evidence extrinsic to the complaint. *See Terenkian v. Republic of Iraq*, 694 F.3d 1122, 1131 (9th Cir. 2012); *Robinson*, 586 F.3d at 685; *Safe Air for Everyone*, 373 F.3d at 1039. A factual challenge “can attack the substance of a complaint’s jurisdictional allegations despite their formal sufficiency.” *Dreier v. United States*, 106 F.3d 844, 847 (9th Cir. 1996) (citation and quotation marks omitted).

B. Motion to Dismiss Under Rule 12(b)(6)

A motion to dismiss for failure to state a claim may be granted only when there is no cognizable legal theory to support the claim or when the complaint lacks sufficient factual allegations to state a facially plausible claim for relief. *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1041 (9th Cir. 2010). In evaluating the sufficiency of a complaint’s factual allegations, the court must accept as true all well-pleaded material facts alleged in the complaint and construe them in the light most favorable to the non-moving party. *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1140 (9th Cir. 2012); *Daniels-Hall v. Nat’l Educ. Ass’n*, 629 F.3d 992, 998 (9th Cir. 2010). To be entitled to a presumption of truth, allegations in a complaint “may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself

effectively.” *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). All reasonable inferences from the factual allegations must be drawn in favor of the plaintiff. *Newcal Indus. v. Ikon Office Solution*, 513 F.3d 1038, 1043 n.2 (9th Cir. 2008). The court need not, however, credit the plaintiff’s legal conclusions that are couched as factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). In addition, a complaint must contain sufficient factual allegations to “plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation.” *Baca*, 652 F.3d at 1216. “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 663 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). All of these principles apply with equal force both to a claim stated in a complaint and a counterclaim stated in a responsive pleading. See *Baca*, 652 F.3d at 1216.

C. Motion to Strike

The purpose of a motion to strike under Rule 12(f) of the Federal Rules of Civil Procedure is to avoid spending time and money litigating spurious issues. *Whittlestone, Inc. v. Handi-Craft Co.*, 618 F.3d 970, 973 (9th Cir. 2010); see also *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (9th Cir. 1993), *rev’d on other grounds*, 510 U.S. 517 (1994). The disposition of a motion to strike is within the discretion of the district court. See *Fed. Sav. & Loan Ins. Corp. v. Gemini Mgmt.*, 921 F.2d 241, 244 (9th Cir. 1990). A court may strike an affirmative defense under Rule 12(f) if it presents “an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f).

An answer “must affirmatively state any avoidance or affirmative defense.” Fed. R. Civ. P. 8(c)(1). Such defenses must be stated “in short and plain terms.” Fed. R. Civ. P. 8(b)(1)(A). An affirmative defense may be insufficient as a matter of pleading or as a matter of law. See
 PAGE 4 – OPINION AND ORDER

Wyshak v. City Nat'l Bank, 607 F.2d 824, 827 (9th Cir. 1979) (addressing an affirmative defense that was insufficiently plead); *Fantasy*, 984 F.2d at 1527 (addressing legally insufficient pleadings). “The key to determining the sufficiency of pleading an affirmative defense is whether it gives plaintiff fair notice of the defense.” *Wyshak*, 607 F.2d at 827 (citation omitted); *see also Simmons v. Navajo Cnty., Ariz.*, 609 F.3d 1011, 1023 (9th Cir. 2010). Rule 12(f) provides that pleadings that are “immaterial” or “impertinent” may be struck by a court. Such pleadings are legally insufficient because they clearly lack merit “under any set of facts the defendant might allege.” *Polk v. Legal Recovery Law Offices*, 291 F.R.D. 485, 489 (S.D. Cal. 2013) (citation and quotation marks omitted). An “immaterial” matter is “that which has no essential or important relationship to the claim for relief or the defenses being pleaded.” *Fantasy*, 984 F.2d at 1527 (quoting C. Wright, A. Miller, et al., 5C Fed. Prac. & Proc. Civ. § 1382 (3d ed. 2013)). “Impertinent” matters are those “that do not pertain, and are not necessary, to the issues in question.” *Id.*

BACKGROUND

On September 12, 2013, the Government brought this action pursuant to the FDCA to enjoin and restrain Defendants from violating the FDCA and FDA regulations. Pl.’s Compl., ECF 1. Defendants in this case include James G. Cole, Inc. (“the firm”), a privately-held Oregon corporation, James G. Cole, the firm’s President, Secretary, and sole board member, and Julie D. Graves, who is alleged to be the firm’s General Manager. Pl.’s Compl. ¶¶ 4-6; Defs.’ Answer, ECF 6 at 2 ¶¶ 4-6. The Government alleges that Defendants have manufactured, promoted, and distributed more than 47 products and that these products are either: (1) unapproved drugs under the FDCA and distributed in interstate commerce; (2) misbranded drugs because the product labels do not bear adequate directions of use; or (3) dietary supplements that were not

manufactured in accordance with current good manufacturing practice (“cGMP”) regulations for dietary supplements. Pl.’s Compl. ¶¶ 1.a.-e., 4, 7, 11-16, 30; Defs.’ Answer at 2 ¶¶ 4, 7.

As relief, the Government seeks a “statutory injunction” under 21 U.S.C. § 332(a), which authorizes district courts “for cause shown[,] to restrain violations of section 331 of this title.” Because the Government seeks a “statutory injunction,” as opposed to an injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure or under traditional equity doctrines, after the Government has established a violation of the FDCA, the Court presumes the Government has proven irreparable injury “because the passage of the [FDCA] is itself an implied finding by Congress that violations will harm the public.” *United States v. Nutri-cology, Inc.*, 982 F.2d 394, 398 (9th Cir. 1992). The specific injunction sought by the Government would enjoin and restrain Defendants from, in relevant part: (1) introducing or delivering, or causing to be introduced or delivered, into interstate commerce (a) any new drug that is neither approved nor exempt from approval under the FDCA, (b) any misbranded drug, and (c) any adulterated dietary supplements; (2) causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded because their labeling fails to bear adequate directions for use; and (3) causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated. Pl.’s Compl. ¶¶ I-III.

On November 18, 2013, Defendants filed an Answer to the Government’s Complaint, asserting four affirmative defenses and submitting a counterclaim for return of property. Defendants’ counterclaim requests the return of 47 TurboSonic exercise machines seized in the District of Oregon on April 11, 2011, by the FDA and retained by the FDA thereafter. Defs.’ Answer at 6 ¶¶ 1-3. Moreover, Defendants assert four separate affirmative defenses alleging that the firm’s products pose no public health danger, that Defendants have acted reasonably and in

good faith in all efforts to comply with applicable FDA regulations, that any injunction on the firm limiting the publication of customer testimonials would violate the First Amendment to the United States Constitution, and that Julie D. Graves is not in fact currently in a management position with the firm and lacks control over its daily activities. Defs.’ Answer at 5-6 ¶¶ 1-4.

DISCUSSION

A. Motion to Dismiss Defendants’ Counterclaim

The Government moves to dismiss Defendants’ counterclaim under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). The Government argues that Defendants’ counterclaim fails to establish subject-matter jurisdiction and fails to allege facts supporting all the material elements to sustain recovery under a viable legal theory. *See Safe Air for Everyone*, 373 F.3d at 1039; *Baca*, 652 F.3d at 1216.

Defendants’ counterclaim requests “the return of property under rule 42(g),”¹ and alleges that: (1) “James G. Cole is the owner of approximately 47 TurboSonic exercise machines seized in this District and retained by the FDA since April 11, 2011”; (2) “Cole seeks the return of these TurboSonic devices at this time because they belong to Cole and can be sold lawfully and with proper representations about their use and limitations and they are not needed as evidence in any criminal proceeding”; and (3) “The FDA has no just cause to seek their continued retention.” Defs.’ Answer at 6 ¶¶ 1-3.

Under Federal Rule of Criminal Procedure 41(g), “[a] person aggrieved by an unlawful search and seizure of property or by the deprivation of property may move for the property’s return.” When a motion under Rule 41(g) is “made by a party against whom no criminal charges

¹ The Government and Defendants both agree that Defendants’ counterclaim should be submitted pursuant to Federal Rule of Criminal Procedure (“Criminal Rule”) 41(g), rather than Federal Rule of Criminal Procedure 42(g) as Defendants erroneously cited in their counterclaim.

have been brought, such a motion is in fact a petition that the district court invoke its civil equitable jurisdiction.” *United States v. Comprehensive Drug Testing, Inc.*, 621 F.3d 1162, 1172 (9th Cir. 2010). Because such a motion is treated as a civil equitable proceeding, “a district court must exercise ‘caution and restraint’ before assuming jurisdiction.” *Ramsden v. United States*, 2 F.3d 322, 324 (9th Cir. 1993) (quoting *Kitty’s East v. United States*, 905 F.2d 1367, 1370 (10th Cir. 1990)). The district court must balance “four discretionary factors to determine whether to allow the government to retain the property, order it returned or . . . craft a compromise solution that seeks to accommodate the interests of all parties.” *Comprehensive Drug Testing, Inc.*, 621 F.3d at 1173. These factors include:

- 1) whether the Government displayed a callous disregard for the constitutional rights of the movant; 2) whether the movant has an individual interest in and need for the property he wants returned; 3) whether the movant would be irreparably injured by denying return of the property; and 4) whether the movant has an adequate remedy at law for the redress of his grievance.

Ramsden, 2 F.3d at 325. After a district court treats a Criminal Rule 41(g) motion as a *civil* complaint, “it [is] required to apply the Federal Rules of Civil Procedure.” *United States v. Ibrahim*, 522 F.3d 1003, 1008 (9th Cir. 2008).

The Government’s first contention, that Defendants fail to meet their burden of establishing subject-matter jurisdiction over their counterclaim, is a facial attack to the sufficiency of Defendants’ answer. *See Safe Air for Everyone*, 373 F.3d at 1039. The Government argues that Defendants must allege facts supporting the four *Ramsden* factors that establish equitable jurisdiction under Criminal Rule 41(g). Namely, the Government contends that there are no allegations related to whether: (1) the Government displayed a callous disregard for the constitutional rights of Defendants; (2) Defendants would be irreparably injured by denying return of the property; and (3) Defendants have an adequate remedy at law for the

redress of their grievance. The Government further argues that because Defendants' counterclaim fails to establish subject-matter jurisdiction, Defendants also fail to plead adequately a claim for the equitable relief sought. *See Iqbal*, 556 U.S. at 663; *see also Baca*, 652 F.3d at 1216.

Defendants respond that they do not need to allege the *Ramsden* factors at the pleading stage in order for this Court to have jurisdiction. Moreover, Defendants assert that they can readily amend their pleadings under Federal Rule of Civil Procedure 15(a)(2) to allege facts supporting the *Ramsden* factors.

In order for the Court to invoke jurisdiction under Criminal Rule 41(g), Defendants must allege sufficient facts to support the Court's invocation of its equity jurisdiction. *See Ramsden*, 2 F.3d at 324. Where the assertion that the allegations contained in the complaint are insufficient to invoke federal jurisdiction, dismissing under Fed. R. Civ. P. 12(b)(1) for lack of jurisdiction is proper. *Safe Air for Everyone*, 373 F.3d at 1039. Furthermore, a claim must contain sufficient factual allegations to "plausibly suggest an entitlement to relief." *Baca*, 652 F.3d at 1216. Defendants concede that they have not alleged facts supporting all the *Ramsden* factors. Defs.' Resp., ECF 13 at 7-8. Based on the Defendants' insufficient pleadings, the Court cannot, even assuming the truth of Defendants' pleadings, conclude that the Court has subject-matter jurisdiction over Defendants' counterclaim pursuant to Rule 12(b)(1). Further, drawing all reasonable inferences in favor of Defendants, the Court finds that there are factual allegations lacking under Rule 12(b)(6) that are needed for the Court to find that Defendants are entitled to the return of property.

Therefore, the Government's motion to dismiss is granted without prejudice and Defendants may amend their counterclaim to address the jurisdictional elements required in an

action under Criminal Rule 41(g). The Court does not at this time reach the merits of whether the Court will exercise its equitable jurisdiction under Rule 41(g).

B. Motion to Strike Defendants' Affirmative Defenses

1. Defendants' First Affirmative Defense

The Government moves to strike Defendants' First Affirmative Defense from the pleadings. Defendants' First Affirmative Defense states:

There is no public health danger presented by Maxam because despite all the allegations to the contrary by the FDA, it has admitted that it has no evidence of even one claim by any customer of any injury or illness as a result of the use of any Maxam products, despite the fact that in excess of one hundred thousand bottles of these products has been distributed.

Defs.' Answer at 5 ¶ 1. The Government argues that even assuming Defendants' First Affirmative Defense to be true, those facts would not relieve Defendants from liability. Defendants respond that their First Affirmative Defense is relevant to the Government's requested relief of a permanent injunction. Because the Government seeks to limit the sale of any future Maxam products until after the FDA finds them in compliance with the FDCA, Defendants argue that the safety of these products is at least a relevant consideration for this Court. *See* Pl.'s Compl. ¶ III.

The Court denies the Government's motion to strike Defendants' First Affirmative Defense. The Court allows Defendant's First Affirmative Defense to remain and reserves ruling on whether the public health danger of Maxam products is a relevant consideration for the question of relief if liability is proven.

2. Defendants' Second Affirmative Defense

Defendants' Second Affirmative Defense states:

The defendants have acted reasonably and in good faith in an effort to comply with all applicable FDA regulations since receiving the

warning letter in October, 2010 and, therefore, the plaintiff should not be allowed the shut-down injunction it seeks. Instead of an injunction shutting down the Maxam business until it engages in the prohibitively costly undertakings sought by the FDA, this Court, after hearing on the current state of operations at Maxam, should enter a much less costly injunction directing that the compliance that Maxam has commenced shall continue in the manner directed by this Court, with monitoring as deemed appropriate by the Court.

Defs.' Answer at 5 ¶ 2. The Government argues that the issue of good faith or making reasonable efforts to comply with the FDCA or FDA regulations is not a defense to an allegation of adulteration, misbranding, or distribution of an unapproved drug under the Act. Defendants respond that their good faith and efforts to comply are relevant to the Court's issuance of a permanent injunction—the remedy requested by the Government. *See United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 176 (9th Cir. 1987).

The Court denies the Government's motion to strike Defendants' Second Affirmative Defense. The Court finds that Defendants' Second Affirmative Defense is relevant to the issuance and scope of any injunction that may be issued if liability is proven. *See* 21 U.S.C. § 332(a); *United States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 854 (9th Cir. 1995) (holding that a "cognizable danger of recurrent violations" is relevant in issuing a permanent injunction under the FDCA (citation and quotation marks omitted)).

3. Defendants' Third Affirmative Defense

The Government moves to strike Defendants' Third Affirmative Defense. This affirmative defense states:

To the extent that the FDA seeks an order prohibiting the publication by Maxam of truthful testimonials written by its customers, such an order would impinge upon the free-speech rights of Maxam, its employees, and its customers, and thus should not be ordered if the testimonials are accompanied by a disclaimer to the effect that the content of the testimonial is not approved by the FDA and represents only a statement about the products

involved based on the experience of the customer or customers making the testimonial. Any order prohibiting testimonials accompanied by such a disclaimer would violate the First Amendment rights of Maxam, its employees, as well as its customers.

Defs.’ Answer at 5-6 ¶ 3. The Government contends that Defendants’ speech (and related testimonials) may be used to demonstrate the intended use of Defendants’ products, and the Government has no intention of seeking an order prohibiting protected speech. Defendants respond that the injunctive relief requested by the Government would ban third-party testimonials regarding Maxam products.

The Court denies the Government’s motion to strike Defendants’ Third Affirmative Defense. If a violation of the FDCA or FDA regulations is proven, evidence regarding the nature of the customer testimonials would pertain to and be necessary to address the proper exercise of this Court’s equitable authority. *See C. Wright, A. Miller, et al., 5C Fed. Prac. & Proc. Civ. § 1382* (3d ed. 2013) (explaining that if “proof concerning [the challenged material] could be received at trial . . . then the matter is not immaterial and impertinent” and that “allegations that may assist the court in determining difficult questions of law” are typically not be struck under Rule 12(f)).

4. Defendants’ Fourth Affirmative Defense

The Government moves to strike Defendants’ Fourth Affirmative Defense on two grounds: (1) Defendants’ admission in their answer negates the defense; and (2) Defendants fail to allege sufficient facts to support this affirmative defense. Defendants’ Fourth Affirmative Defense states:

As a separate Affirmative Defense on behalf of Julie Graves, she is no longer in a management position at Maxam, has no ownership interest, and has no ability to control or alter any of its marketing activities, any of its product handling, nor any other act which might be the subject of the relief sought by the FDA; and

accordingly no injunctive order should enter against her because she has no ability to take any action to comply with such order.

Defs.' Answer at 6 ¶ 4.

The Court finds that Defendants' pleadings on this issue are inconsistent. Defendants admit in their Answer, in conflict with their Fourth Affirmative Defense, that "Defendant Julie D. Graves is the firm's General Manager and controls the day-to-day operations of the firm's facilities." Defs.' Answer at 2 ¶ 6; Pl.'s Compl. ¶ 6. The Court grants the Government's motion to strike Defendants' Fourth Affirmative Defense and also grants Defendants leave to amend. Defendants also have leave to amended their answer pursuant to Federal Rule of Civil Procedure 15(a)(2) to clarify whether Ms. Graves is or is not currently Maxam's general manager and in control of operations at the Maxam facility.

CONCLUSION

The Government's Motion to Dismiss Defendants' Counterclaim and Strike Defendants' Affirmative Defenses (ECF 11) is GRANTED IN PART and DENIED IN PART. Defendants' Counterclaim is dismissed without prejudice, and Defendants are granted leave to amend. The Court strikes Defendants' Fourth Affirmative Defense with leave to amend. The Court denies the Government's motion to strike Defendants' First, Second, and Third Affirmative Defenses.

IT IS SO ORDERED.

DATED this 31st day of March, 2014.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge